Testimony of Richard F. Kingham
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Mr. Chairman, thank you for inviting me to testify before this Subcommittee. My name is Richard F. Kingham. I am a partner in the law firm of Covington & Burling, where I have practiced in the area of food and drug law for more than 31 years. During this time, I have represented pharmaceutical companies and industry associations in numerous proceedings before the Food and Drug Administration and other federal agencies. I have also advised clients with respect to product liability actions and the relationship between tort liability and the FDA drug approval process. I have served on committees of the National Institutes of Health and the Institute of Medicine of the National Academy of Sciences and have taught food and drug law and related subjects at the University of Virginia School of Law, the Georgetown University Law Center, and the University of Wales in the UK. I am testifying in my personal capacity at the request of the Committee, and am not representing any client.

My statement addresses the proposal to provide a defense to punitive damages for manufacturers and distributors of drugs, biological products, and medical devices that have been subject to premarket approval, licensure, or clearance by FDA. Language to enact this type of protection included in section 7(c) of H.R.5 as passed by the House in the 108th Congress. I support the passage of legislation creating a carefully worded, narrow defense that is based on the language in that bill.

A defense like that proposed in H.R.5 will protect against the imposition of punitive damage judgments against manufacturers, but only under very limited circumstances. The defense will not prevent any person from bringing a claim against a drug or device manufacturer. Injured patients will continue to be able to have their day in state court.

Furthermore, the defense is narrowly crafted so that it will not prevent an injured patient from being awarded full compensation in any case. The full range of compensatory damages, including substantial awards for pain and suffering, will still be available to plaintiffs. The bill will provide only a narrow defense to the award of punitive damages.

Moreover, only defendants that have complied in all relevant respects with FDA requirements are eligible to use this defense. FDA not only conducts a demanding and comprehensive safety assessment before each product reaches the market, but also continues to review the product's safety over its life on the market. Although the need for certain changes and reforms in FDA's review process recently has been the subject of debate, the agency's current structure and processes do support the goal of providing a comprehensive review. To facilitate this review, FDA imposes extensive reporting requirements on the manufacturers of drugs, biological products, and medical devices. Any manufacturer that knowingly misrepresents or withholds required information from FDA, and thus potentially distorts or subverts the FDA review process, will be unable to use this statutory defense against punitive damages.

A review of even a few steps of the FDA review process for prescription pharmaceutical products reveals both the scope of the information that manufacturers must submit to FDA and to the breadth and depth of FDA's product review. I choose to focus on prescription drugs today because these products have been the topic of much discussion in recent months. The requirements for medical devices and biological products, including vaccines, are similar in breadth.

In applying for FDA approval of a new prescription drug, the manufacturer is required to submit to FDA all known safety information about the drug, including information obtained in clinical trials in the U.S. and in foreign countries. As part of this application, the

manufacturer must submit the results of affirmative large-scale studies of the drug's safety and effectiveness. These studies often involve several thousand patients at multiple locations. New Drug Applications (NDAs) literally can reach hundreds of thousands of pages in length.

As part of a drug's approval, FDA may require the manufacturer to conduct additional studies and submit reports. These postmarketing studies provide additional data and may allow the manufacturer and the agency to identify rarely-occurring adverse events that could not have been identified in clinical trials of even thousands of patients.

Whether or not postmarketing studies are required, the drug manufacturer must report to the agency a wide range of information about each marketed drug on an ongoing basis. For instance, the manufacturer must report to FDA adverse events that occur anywhere in the world, whether or not the company thinks that the event is caused by the drug. Any issues arising in the manufacturing process must be reported, as well. For instance, if even one batch of a distributed drug fails to meet a single manufacturing specification, FDA must be notified within 3 days. In annual reports to FDA, the manufacturer must submit the reports of any clinical trial conducted inside or outside of the U.S. The manufacturer also must notify FDA of any significant regulatory decision that affects the drug by any regulatory agency in the world.

FDA's structure and processes allow the agency to review this information thoroughly and to update potential safety concerns continuously. In its reviewing Divisions, FDA employs hundreds of doctors, each qualified in the relevant scientific discipline. These doctors review individual data points for each drug, as well as the universe of data for similar products, to determine whether the product's benefit-risk ratio has changed and if additional product warnings or limitations are required. To assist in this assessment, FDA employs epidemiologists, statisticians, and microbiologists and has developed technology tailored to the

reviewers' needs such as adverse event databases. Moreover, the agency's advisory committees, of which there is one for each category of drug, are composed of prominent specialists that are not employed by FDA and are required to comply with FDA requirements regarding conflicts of interest. FDA regularly refers technical issues to these committees for additional input.

The combination of mandatory reporting by manufacturers and careful agency review allows FDA to identify immediate and unusual safety issues such as manufacturing errors, as well as long-term issues such as rarely-occurring but serious adverse events. The manufacturers clearly play an essential and irreplaceable role in the process.

Manufacturers that act lawfully and in good faith with FDA's requirements -- that submit all required information to FDA and that comply with any limitations that FDA imposes on the product's marketing -- still may be exposed to tort claims of negligence and strict liability under the proposed statutory language. They still may be required to pay compensatory damages. This bill properly would recognize, however, that these manufacturers cannot be deemed to have engaged in the sort of egregious misconduct that would justify punitive damages. Their good faith compliance with the regulatory requirements cannot be viewed as the kind of behavior that would "shock the conscience" of the community and thus deserve to be subject to punitive damages.

Indeed, commentators have urged for years that regulatory compliance be deemed a defense to claims for punitive damages. In 1991, a very distinguished panel writing the Reporter's Study on Enterprise Responsibility for Personal Injury for the American Law Institute asserted that, "If a defendant has fully complied with regulatory requirements and fully disclosed all material information relating to risk and its control, it is hard to justify the jury's freedom to

award punitive damages." The panel argued specifically that "Pharmaceuticals present a special combination of circumstances justifying such a [limited] defense."

Congress itself took that view in passing the 1986 National Childhood Vaccine Injury Act. That Act creates a limited defense to punitive damages for manufacturers of certain vaccines. That provision's limitations are similar to those in the proposed language, in that vaccine manufacturers may invoke the defense only if they can demonstrate their compliance in all material respects with the relevant requirements of the Federal Food, Drug, and Cosmetic Act (FDCA). That legislation has successfully achieved the goals that led to its enactment. Companies developing or testing vaccines for many new uses are not covered by that Act, however.

A large number of states also have taken the view that manufacturers should be able to defend themselves from punitive damages on the basis of their compliance with FDA requirements. Since New Jersey first enacted such a defense nearly 20 years ago, at least seven additional states have created a statutory defense either for FDA-approved products or for all products that comply with mandatory state or Federal government standards. In addition, six other states either prohibit claims for punitive damages more generally or make no provision for the award of punitive damages. Michigan goes even further, providing a complete defense to tort liability for products that are FDA-approved and compliant.

Thus, at least 15 states provide defenses that are at least as generous as the language of the proposed bill. There has been no suggestion that these state laws have precluded injured patients from successfully litigating cases of negligence and strict liability against companies manufacturing and distributing drugs, biologics, and medical devices. In fact, the

legal scholars that endorse a limited regulatory compliance defense acknowledge that the defense will affect a relatively limited number of cases.

The language of H.R.5 also appropriately makes the defense unavailable where a person illegally paid or bribed an FDA official to obtain or maintain the approval, clearance, or licensure for the product at issue. Although no innovative pharmaceutical manufacturer has been accused of bribery, and although the concerns regarding generic manufacturers appear to have been resolved, this language remains a necessary and wise precaution.

In summary, this House should enact a carefully crafted, limited defense to punitive damages for products that are subject to and compliant with FDA premarket approval requirements. Under such a provision, no injured person will go uncompensated. No person will receive less than complete compensation. At the same time, the defense will encourage reporting by FDA-regulated companies and will further strengthen the already comprehensive FDA review process for drugs, biological products, and medical devices.